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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/543,014

08/15/2006

Alison Ann Watson

2245.054

4048

23405

7590

12/24/2008

HESLIN ROTHENBERG FARLEY & MESITI PC  
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EXAMINER

LOEWE, SUN JAE Y

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

12/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/543,014	<b>Applicant(s)</b> WATSON ET AL.	
	<b>Examiner</b> SUN JAE Y. LOEWE	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 45-63 is/are pending in the application.
- 4a) Of the above claim(s) 49-53 and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-48, 54-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

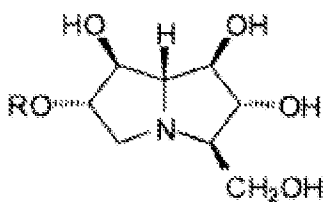
### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7-22-2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of compound of the species in claim 45 in which R is hydrogen and the disease of bacterial infection in the responses dated September 15, 2008 and May 20, 2008 is acknowledged. It is noted that the species read of claims 45-48 and 54-62. It is further noted that claim 46 reads on one enantiomer, ie. the species of



. This enantiomer is taken to be Applicant's elected species (ie. see restriction requirement dated August 11, 2008; page 2; Section 2; 2<sup>nd</sup> paragraph).

2. Claims 49-54 and 63 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject.

3. MPEP § 803.02 provides guidelines for election of species in Markush-type claims. These guidelines were followed for the search and examination detailed herein.

The elected species was not found to be allowable. Furthermore, the Markush-type claims were rejected under 35 USC 112 2<sup>nd</sup> paragraph. Pursuant MPEP 803.02, the provisional election of species was given effect and non-elected species withdrawn from further consideration.

***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on September 22, 2005 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the IDS was considered. A signed copy of form 1449 is submitted herewith.

***Claim Objections***

5. Claims 45-48 and 54-62 objected to for containing non-elected subject matter.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 45-48 and 54-62 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to method of treating “a disease associated with a deleterious immune response.” The scope of the claims cannot be ascertained because “disease associated with a deleterious immune response” is not defined in the specification. Appropriate clarification and correction is requested.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

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obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claims 45-48 and 54-62 rejected under 35 U.S.C. 103(a) as being obvious over Asano et al. in view of Immune-strategy.

Determination of the scope and contents of the prior art.

Asano et al. teaches the elected compound as a glycosidase inhibitor. Immune-strategy teaches glycosidase inhibitor in combination with ZDV for the treatment of HIV. Treatment of HIV encompasses treatment of bacterial infections that result from the disease.

Ascertaining the differences between the prior art and the claims at issue.

The combined teaching of Asano et al. and Immune-strategy results in the instant elected species: ie. method of treating bacterial infections.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.

One of ordinary skill would be motivated to make the modification required to arrive at the instant invention with reasonable expectation of success. The motivation would be to utilize alternate methods for treatment of HIV.

Thus, the instant claims are *prima facie* obvious over the teachings of the prior art.

***Conclusion***

8. No claims allowed.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074.

The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe/  
12-22-2008

/Rebecca L Anderson/  
Primary Examiner, Art Unit 1626